

Q and A on exemption from HSNO

Q: Which veterinary medicines are you seeking an exemption for?

A: Nearly all veterinary medicines should be granted an exemption. These include antibiotics, vaccines, parasite treatments, anti-bacterials and products used in surgical procedures.

Q: Are there any veterinary medicines that you won't be seeking an exemption for and why?

A: Yes. For example, an exemption will not be sought for liquids used to control internal and external parasites in large animals. These products are sold in large quantities, and used in a dispersive manner, and could conceivably pose risks to users and the environment if used, transported, or disposed of improperly.

Q: What are the benefits of an exemption beyond bigger profits for pharmaceutical manufacturers and vets?

A: A reduction in unnecessary and costly regulation. This will lead to a greater range of products at competitive prices. An exemption will also allow ERMA to put more resources into areas where there are real risks to the safety of people and the environment.

Q: What are the common animal health issues/diseases?

A: Infections (eg. mastitis), wounds (eg. cat bite abscess, cuts, abrasions), ear infections, eye infections, dental problems, arthritis, heart problems, dermatitis (skin conditions), fleas and viral infections.

Q: Why were vet medicines included in the HSNO Act in the first place?

A: The HSNO legislation was world leading but it was applied too broadly. The Act was written to cover hazardous substances – chemicals, poisons, flammables, explosives, and corrosives.

Although human medicines were exempted, animal health products were not. This was because they are sometimes used in large quantities and if handled or disposed of incorrectly could present risks to human health and the environment.

However, we are not seeking an exemption for products used in large quantities.

Q: If it was considered necessary to have a double regulation process in the first place, then why isn't it necessary now?

A: See answer above. Generally, for the vast bulk of animal medicines there is no reason for HSNO regulation.

Q: What are the risks to the environment of not having vet medicines regulated by ERMA?

A: The vast bulk of animal medicines are used in small quantities and pose negligible risks to the environment and people. Products used in large quantities or in a dispersive manner, such as pour-on drenches, will not be exempt from HSNO regulation.

Q: You are arguing that human medicines are already exempt and therefore animal medicines should be too, but how similar are they?

A: Some are very similar. Some products that have been developed for humans are also effective treatments for farm animals and pets. Others are not similar at all as they are designed for the particular biological and health requirements of a farm animal or pet. The main similarity is that both human and veterinary medicines pose negligible risks to the environment or people and can be adequately regulated by the NZ Food Safety Authority.

Q: If an exemption will reduce compliance costs for the \$250 million a year animal health industry, will that translate into cheaper vet medicines for primary producers and animal owners?

A: The main benefit for pet owners, farmers and vets is likely to be a greater range of treatments for their animals and therefore a more competitive market.

Q: Who else is showing support for an exemption?

A: Federated Farmers of New Zealand, the New Zealand Veterinary Association, and industry association Animal Remedy and Plant Protection Association (ARPPA). There has also been support from other primary industry associations and the New Zealand Food Safety Authority, which is one of the two regulators of vet medicines.

Q: What is the total cost of ERMA's regulation of these medicines currently?

A: Hard to say. A conservative estimate is that HSNO compliance costs industry about one percent of turnover, or \$2.5 million every year.

Q: What is the HSNO regime?

A: The Hazardous Substances and New Organisms Act (HSNO) Act 1996 is an environmental and health and safety law which promotes the safe, innovative use of hazardous substances and new organisms. Anybody who wants to introduce a new hazardous substance or new organism into New Zealand must apply to the Environmental Risk Management Authority (ERMA) for approval. Approvals will place controls or conditions on the substance or organism to manage its effects and risks. All users must comply with these conditions.

Q: What is the Global Harmonised System?

A: A United Nations classification and labelling framework. The GHS is the basis for the HSNO regime. The HSNO regime is being reviewed currently to match the latest changes to GHS.

Q: Why are the HSNO regulations being reviewed now?

A: After nine years, the HSNO regime is being reviewed to bring it into line with the latest Globally Harmonised System. Industry is supporting the review and sees an exemption as one of the best outcomes.

Q: What does HSNO assess the veterinary medicines for?

A: There are nine types of hazard. Many of them – including explosives, flammables, gases under pressure – are not relevant. The areas which may apply to veterinary medicines are ‘skin irritation’ or ‘substances that may be harmful if swallowed’ or ‘harmful in the aquatic environment’.

Q: Will NZFSA look at additional aspects of the medicines – some of the things currently covered by ERMA - if it becomes the sole regulator?

A: In 2007 the Food Safety Authority was given new powers to examine the risks to public health. This would cover off some risks presently falling under the HSNO regime. Other risks can be managed by vets and other legislation such as the Misuse of Drugs Act.

Q: Will less regulation really result in a wider range of innovative medicines, or will it just put more money into vets’ and pharmaceutical companies’ pockets?

A: The animal health market in New Zealand is small and very competitive. According to the latest Index of Veterinary Specialities Manual, there are 50 veterinary medicine companies operating in the New Zealand market. The main goal is to do away with unnecessary regulation, and open the way for a greater range of treatment options for vets, farmers, and pet owners, at more competitive prices.

Q: What is ERMA’s position on this?

A: ERMA is considering submissions on a range of proposals to review HSNO, including possible new exemptions. It will make a recommendation to the Minister for the Environment in the next few weeks or months on possible changes.

Q: Should the exemption cover all pack sizes?

A: The exemption should ideally cover all veterinary medicines sold in primary packaging of less than or equal to 500 mls or 500 grams. That means paraciticides which are typically sold in 20 litre drums for large animals will not be exempt.